SEP - 7 2001

K011816

VIII. 510(k) Summary of Safety and Effectiveness

Date prepared

June 08, 2001

Company Name and Address

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Contact Person: Dr. Jörg Stein
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Device Name

Proprietary Name: Mini Multileaf Collimator
Common Name: Therapeutic X-Ray Collimator

Classification

Proposed Regulatory Class: II
Device Classification: 892.5710

Therapeutic X-Ray Collimators have been classified by the Radiology Devices Panel as Class II devices (21 CFR 892.5710, Product Code IXI).

Predicate Device

The Mini Multileaf Collimator is substantially equivalent to the MRC Motorized Micro Multileaf Collimator (K000349).

Device Description

The Mini Multileaf Collimator is a conformal radiation therapy and radiosurgery device that is mounted to a standard radiation therapy linear accelerator (Linac). The Mini Multileaf Collimator receives input from planning software that determines the collimator aperture shapes at different gantry positions along the arc around the target area. Radiation is delivered at a constant rate.

The Mini Multileaf Collimator consists of three parts: (1) the user console, (2) the control cabinet and (3) the collimator mechanism.

The control cabinet with the user console serve as the control station for the operator and are located near the Linac operator console. The control cabinet contains the PC, an interface board and the power supply. The PC consists of a specified configuration of a CPU, motherboard, RAM, VGA board and HDD. It is used as the communication interface between the operator and the planning system software that contains the treatment positioning data. The PC also serves as the master for the control and verification system. The data received from the planning system

software is processed and transferred to the micro-controllers (MC) on the control and verification boards.

The operator at the console initiates position adjustment. The PC then starts all the MC's simultaneously and retrieves the position of the leaves, comparing the values of the control system with those of the verification system.

The collimator mechanism is fitted to the accessory holder of the Linac gantry. It consists of 80 driving units that position the tungsten leaves via a rack and pinion mechanism. A potentiometer is directly connected with each tungsten leaf to retrieve information on the leaf position. Independent potentiometers for verification are also included in the driving units.

Intended Use

The Mini Multileaf Collimator is a conformal radiation therapy and radiosurgery device that delivers a shaped X-ray beam from a radiation therapy source. The Mini Multileaf Collimator is attached to a linear accelerator and consists of a series of pairs of tungsten leaves that collimate radiation delivery to a target based on a treatment plan generated by planning software. The device is used to help the clinician deliver well-defined target volumes of radiation while sparing the surrounding tissues and organs. The Mini Multileaf Collimator should only be used for fixed field X-ray treatments.

Summary of Technological Characteristics Compared to Predicate Device

Similarities

The intended use and the indications for use are the same. Both the cleared unmodified and the modified device are conformal radiation therapy and radiosurgery devices that are attached to a standard radiation therapy linear accelerator (Linac) capable of shaping an X-ray beam.

Both devices consist of a series of pairs of motorized parallel tungsten leaves that collimate the radiation delivery to a target according to a treatment plan generated by treatment planning software.

Minor Differences

To achieve a larger maximum field size a somewhat different electromechanical design had to be employed, including

- different design of drive mechanism
- focused instead of non-focused leaves
- different type of leaf bearings

The above described changes in the electromechanical design required/enabled minor changes to the electronic design:

- Control boards could be integrated in the Mini Multileaf Collimator enclosure enabling easier handling for the operator
- Independent real time operating system PC integrated in Windows-PC driving Micro Controllers (rather the Windows-PC itself)

The hardware changes required some minor software changes, which did not raise any new safety/effectiveness questions and did not change the "level of concern".

The results of the Risk Management, Verification, Validation and other testing activities indicate that the differences between the modified and the unmodified device do not raise new questions about safety and effectiveness. All tests were executed with all acceptance criteria met.

The modified device (Mini Multileaf Collimator) is substantially equivalent to the unmodified device (Motorized Micro Multileaf Collimator).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 7 2001

Dr. Jörg Stein
Managing Director
MRC Systems GMBH
Hans-Bunte-Strasse 10
D-69123 Heidelberg
GERMANY

Re: K011816
Mini Multileaf Collimator Model KMI, Version 1.2
Dated: June 8, 2001
Received: June 11, 2001
Regulatory Class: II
21 CFR 892.5710/Procode: 90 IXI

Dear Dr. Stein:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4,xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for use enclosure

510(k) number (if known): K001816

Device name: Mini Multileaf Collimator

Indications for Use:

The Mini Multileaf Collimator is a conformal radiation therapy and radiosurgery device that delivers a shaped X-ray beam from a radiation therapy source. The Mini Multileaf Collimator is attached to a linear accelerator and consists of a series of pairs of tungsten leaves that collimate radiation delivery to a target based on a treatment plan generated by planning software. The device is used to help the clinician deliver well-defined target volumes of radiation while sparing the surrounding tissues and organs. The Mini Multileaf Collimator should only be used for fixed field X-ray treatments.

(Please Do not write below this line – continue on another page if needed)

Concurrence of CDRH, Office of device evaluation (ODE)

Prescription Use ✓ OR Over-the-counter-use_____
(per 21 CFR 801.109)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K011816

(optional format 1-2-96)